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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,097	11/08/2005	Samuel I. Stupp	NANO 106 US2 (NU 22088)	2444
62249	7590	10/19/2007	EXAMINER	
BENET GROUP LLC C/O INTELLEVATE P.O. BOX 52050 MINNEAPOLIS, MN 55402			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/534,097	Applicant(s) STUPP ET AL.	
	Examiner Samuel W. Liu	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 4-6 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-6 and 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/20/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

#### *Status of the claims*

Claims 4-6 and 12-14 are pending.

The amendment filed 8/21/07 which cancels claims 1-3 and 7-11, adds claims 12-14, and amends claims 4-5 has been entered. The applicants' request (filed 8/21/07) for extension of time of one month has been entered.

#### *Withdrawal of the objections*

- The objection to the Spec is withdrawn in light of the amendment the Spec.
- The rejection to claims 4-6 is withdrawn in light of the amendment of the claims 4-5.

#### **IDS**

The references cited in the IDS filed 7/20/07 have been considered by Examiner.

#### ***Reiterated-Continuing data and priority***

This application is a continuation application of 09561226 filed 4/28/2000 (now US Pat. No. 6924264). Applicant's claim for the benefit of a prior-filed application 60425536 filed 11/12/2002 and 60425689 filed 11/12/2002 under 35 U.S.C. 119(e) is acknowledged. Yet, it is of note that 60425536 has no adequate support for the claimed invention of instant claims 4-6 (see below). Thus, this application does not have the benefit of prior filed 60425536 filed 11/12/2002.

#### ***New-Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 4-6 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement; this is a new matter rejection. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of “minerals nucleate at the nanofiber surface”, which as amended into claim 4 on 8/21/07, is not supported in the specification as originally filed. Applicant can either cancel the new matter or point out specification support for the phrase in the specification as originally filed.

At page 8, the response filed 8/21/07 asserts that support for claim 4 can be found in paragraph [0027] and Example 1. The Spec does not teach/describe “minerals nucleate at the nanofiber surface”; paragraph [0027] is completely salient in this regard; and Example 1 (at [0060]) sets forth “the peptide-amphiphile nanofibrils control nucleation and direction of the crystal growth”; however, Example 1 does not teach the nucleation at the nanofiber surface is mediated by the “minerals”. Thus, said limitation is a new matter.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 4 and 6 remain, and claims 5 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 4 (*maintained*) is unclear in “one ionically charged species of peptide amphiphile” (lines 2-3) because the claim does not make it clear (i) whether or not said “species” (in the first solution) is not homogenous, i.e., some peptide amphiphiles have ionically charged species while the other do not, and (ii) whether or not said “ionically charged species” refers to net negatively or positively charged molecule, or zwitterions. The Spec does not define said “ionically charged species”. The dependent claims 5-6 and 12-14 which do not cure the defect of claim 4 are included in the rejection.

Claims 5 and 12 (*new*) lack antecedent basis of “said materials” because claim 4 from which claim 5 depends does not recite “materials” thereof.

*The applicants' response to the rejection under 35 USC 112, second paragraph*

The response filed 8/21/07 argues that as applicants have amended claim, the rejection should be withdrawn. This is found unpersuasive because the amendment of claim 4 does not cure the defect.

***Claim Rejections - 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

- Claims 4-6 remain and claim 14 is rejected under 35 U.S.C. 102(a) as being anticipated by Wong et al. (*Nano Lett.* (2002, June) 2, 583-587).

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Wong et al. teach a process of preparing  $\text{SiO}_2/\text{Au}$  composite on out-surface of nanoparticles (see Scheme 1, page 585) that contain self-assembled peptide amphiphiles ( $\text{Lys}_{200}\text{Cys}_{30}$ ) by mixing the solution (A) that comprises hydrogen bromide salt of  $\text{Lys}_{200}\text{Cys}_{30}$  (see Figure 1 legend) with  $\text{SiO}_2$  solution (B). Solution (A) also called “Au solution” (see line 4 of Figure 1 legend) further comprises Au salts which are prepared by citrate reduction taught by the incorporated reference 32 (see “*Discussion of art*”), i.e.,  $\text{Au}^{3+}$  has the same signed ionic charge as positively charged Lys  $\epsilon$ -amine group in aqueous solution. Here, the  $\text{SiO}_2/\text{Au}$  composite are ionically charged species; solution A is equivalent to instant “first solution” and solution B to instant “second solution”. In solution B, the  $\text{SiO}_2$  (colloidal particles of  $\text{SiO}_2$  are negatively charged, due to  $\text{O}^-$  or  $\text{O}^{2-}$ , see “*Discussion of art*”), i.e., solution B contains ions having opposite signed charge to  $\text{Au}^{3+}/\text{Lys}_{200}\text{Cys}_{30}$ . Since mineral “Au” ions has inherent property of acting as nucleation sites for formation of gold nanoparticles (see “*Discussion of art*”), Wong et al. inherently the method of claim 4.

Wong et al teach that formation of  $\text{Au}^{3+}/\text{Lys}_{200}\text{Cys}_{30}$  nanofibers and  $\text{SiO}_2/\text{Lys}_{200}\text{Cys}_{30}$  nanofibers is time-dependent, e.g., the formation of  $\text{SiO}_2/\text{Au}^{3+}/\text{Lys}_{200}\text{Cys}_{30}$  nanoparticles emerges after reaction of the solution A with solution B (see Figure 1 legend, lines 7-8). Since the reaction time is inherently relative to controlling size and growth of the materials ( $\text{SiO}_2/\text{Au}$ ) on the amphiphilic peptides, the above Wong’s teachings anticipate claims 5.

Wong et al. teach pH-dependent charge state for lysine  $\epsilon$ -amino groups and  $\text{SiO}_2$  (see left column, 2<sup>nd</sup> paragraph, lines 16-22, page 584) and teach that the pH of the solution mixture is 4 (right column, lines 1-2), suggesting a requirement of adjusting pH, which anticipates claim 6.

Scheme 1 shows that the ration of negatively charged silica nanoparticles ( $n\text{-SiO}_2$ ) (see page 584, left column, lines 4-5 from the bottom) to “gold” particles “ $n\text{-Au}$ ” is about 2:1, indicating the resultant nanostructure has net negative charge, which anticipates claim 14.

- Claims 4-6 are again rejected under 35 U.S.C. 102(a) as being anticipated by Slocik et al. (*Nano Lett.* (2002, March) 2, 169-173).

In abstract and at page 170, left column, Slocik et al. teach preparation of nanomaterial comprising histidine-rich self-assemble amphiphilic peptides (HREs) and “metal sulfide composite”, wherein HREs stabilize nanoclusters (page 172, left column, lines 7-9 of last paragraph). At page 173, left column, lines 18-25, Slocik et al. teach addition of the solution of  $\text{AgNO}_3$  to an aqueous solution of peptide followed by dilution with Tris buffer, 0.10 M, pH 8.6 under the condition of histidine-side chains possessing positive charges, and thus having the same signed charges as  $\text{Ag}^+$  ions. Such the resultant solution, i.e., solution (A) is equivalent to instant “first solution”.

Further, Slocik et al. teach addition of an aqueous solution of  $\text{Na}_2\text{S}$ , i.e., solution (B), equivalent to instant “second solution”, to solution (A) to produce  $\text{Ag}_2\text{S}$ /HREs nanofibers.

At page 170, left column, last paragraph, Slocik et al teach the nucleation of nanomaterial is mediated by addition of mineral “inorganic sulfide”. Thus, Slocik et al. teach the method of claim 4.

In the above preparation process, the dilution with Tris buffer, pH 8.6, is comparable to adjusting pH of the solution thereof, which anticipates claim 6.

Slocik et al. teach incubation of  $\text{AgNO}_3$  solution with the peptide solution for certain period time, e.g., 15 min, and reaction time for incubating solutions A and B is 4 hour (see left column, page 173), because said reaction time is inherently relative to controlling size and growth of metal sulfide ( $\text{Ag}_2\text{S}$ ) on the amphiphilic peptides, the above Slocik et al. teachings anticipate claims 5.

*The applicants' response to the rejections under 35USC 102*

At page 9, the response filed 8/21/07 submits that Wong et al. fails to teach use of ions of minerals that cause the nucleation of minerals on the surface of a self-assembled peptide amphiphile, i.e., peptide nanostructure, and that Wong et al. do not teach or suggest the mineralization of the nanostructure being formed; accordingly, Wong et al. do not teach every element of the claims. Thus, the response requests for withdrawal of the rejection.

The applicants' arguments are found unpersuasive because, as discussed in the rejection, mineral "Au" ions have inherent property of acting as nucleation sites for formation of gold nanoparticles. Wong et al. clearly teach formation of "n-Au"-"n-SiO<sub>2</sub>" clusters which is considered to be "mineralization" of the nanostructure (shown in Scheme 1, page 585). Wong et al. teach every limitations of the amended claim 4, and therefore, Wong et al. inherently teach the claimed method.

At page 10, the response asserts that Slocik et al do not teach or suggest the mineralization of self-assembled peptide nanostructure as the present invention is directed to a method of making mineralized nanofiber. The response submits that since the amended claims more specifically identify that the "material" being formed on the surface of the nanofiber are



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minerals, and since Slocik et al. do not satisfy each and every element of the claims, the rejection should be withdrawn.

Te applicants' arguments are found unpersuasive because, as discussed in the above rejection, Slocik et al. teach the solutions equivalent to the instant "first solution" and "second solution", and teach mixing these solutions to produce the self-assembled peptide nanoclusters wherein the minerals which mediates nucleation of the nanoclusters formed a coordination complex with the peptides on the nanocluster's surface (see page 171, right column, 2<sup>nd</sup> paragraph, lines 17-21, and page 72, left column, 2<sup>nd</sup> paragraph). Thus, Slocik et al. teach every limitations of the amended claim 4; and therefore, the rejection is proper and maintained. Please note that the independent claim 4 as amended does not recite "material" thereof.

### *Conclusion*

No claims are allowed.

### *Discussion of art*

The prior art made of record and not currently relied upon in any rejections is considered pertinent to Applicants' disclosure:

- Knake et al. (*Langmuir* (205) 21, 1001-1008) teach inherent property of mineral "gold" (Au) seeds that acts as nucleation sites for formation of gold nanoparticles in a polymer (see abstract and page 1006, left column, 2<sup>nd</sup> paragraph).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from

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the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon, can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

*SWL*

Samuel Wei Liu, Ph.D.  
Patent Examiner, Art Unit 1656  
October 10, 2007

*Karen Cochrane Carlson*  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER